

**REMARKS**

This communication is responsive to final Office action mailed November 08, 2006, in which claims 1-27 were pending, with claims 22-27 being withdrawn from consideration.

In the present response claims 1, 9, 13, 15-18, and 21 have been amended, claims 12 and 22-27 have been cancelled, and new claims 28-32 have been added.

Support for the amendments and new claims is found throughout the specification and/or claims as originally filed, and therefore new matter has not been introduced. In particular, see page 6, lines 12-14, which supports the amendment to claim 1; page 18, lines 4-7, which supports the amendment to claim 9; and page 17, lines 15-19, which supports new claims 28-31.

Applicants respectfully request entry of the present amendments, upon which claims 1-11, 13-21, and 28-32 will be pending and in front of the Examiner for consideration.

Applicants submit that these amendments, and the remarks that follow, address the issues regarding patentability of the claimed subject matter, and put the application in condition for allowance.

**Claim Rejections - 35 U.S.C. § 112, Second Paragraph**

**Claims 1-21**

Claims 1-21 were rejected under 35 U.S.C. §112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the Office action, the Examiner asserts that the phrase “polymerization accelerator” in claim 1 is uncertain. While Applicants disagree, to expedite prosecution, claim 1 has been amended to clarify that the polymerization accelerator functions to increase the rate that the polymerizable material becomes incorporated into a polymerized product in a polymerization reaction.

In the Office action, the Examiner also asserts that the phrase “acceptor or reductant” in claim 9 is unclear. Claim 9 has been amended to clarify that the acceptor or

reductant are materials that form free radicals and cause free radical polymerization of the polymerizable material in the polymerization reaction.

In the Office action, the Examiner also asserts that the phrases “albumin binding moieties” and “phospholipid moieties” in claim 10 are uncertain as to functional groups encompassed by the terms.

Applicants respectfully disagree and direct the Examiner’s attention to page 8 lines 26-29 of the Detailed Description, where albumin binding moieties are described in detail. Albumin binding moieties include, for example, long-chain fatty acids such as oleate, stearate, linoleate, and palmitate, all of which known in the art. Given this description, as well as chemical moieties that are known in the art to bind albumin, Applicants assert that one would understand what functional groups are encompassed by this term.

Also at this location in the specification, it is stated that other biocompatible functional groups can be provided by phospholipids, for example, phosphoryl choline, which is also well known in the art.

Applicants direct the Examiner’s attention to page 11, line 20, to page 13, line 6, for direction as to how the accelerator can include a biocompatible functional group.

For example, in Formula III, Z is described as the functional group that can include an albumin binding moiety or a phospholipid moiety. Given the present description and information available to one of skill in the art, one would understand that the phosphate group ( $\text{PO}_4$ ) of the phospholipid moiety could be bonded to the N-vinyl nitrogen, and the glycerol portion of the phospholipid moiety bonded to the phosphate group, and the fatty acid portion bonded to the glycerol portion.

In the Office action, the Examiner also asserts that claims 17 and 18 lack proper antecedent basis for the phrase “polymeric matrix”. The claims have been amended to recite “polymerized product” which has proper antecedent basis from claim 1.

In the Office action, the Examiner also asserts that the phrase “polymerizable material” in claim 21 lacks antecedent basis. Claim 21 has been amended from “polymerizable material” to “macromer” and therefore corrects this informality.

In view of this, Applicants submit the rejection has been overcome and that the pending claims meet the requirements of 35 USC §112.

**Claims Rejections - 35 U.S.C. § 103(a)****Claims 1-10 and 12-21 (Hubbell et al. '914 or '870)**

In the Office action, claims 1-10 and 12-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hubbell et al. (U.S. Pat. No. 5,529,914; herein "Hubbell '914") or Hubbell et al. (U.S. Pat. No. 6,258,870 B1; herein "Hubbell '870"); claim was rejected 11 as being unpatentable over Hubbell '914 or Hubbell '870 in view of Corley *et al.* (U.S. Pat. No. 5,746,935; herein "Corley '935") or Corley *et al.* (U.S. Pat. No. 5,442,035; herein "Corley '035").

In the present response, claim 1 has been amended to recite that the polymerization accelerator comprises an N-vinyl group, which is a preferred feature of the biocompatible polymerization accelerators of the present invention. It is noted that Applicants' claim 31 also includes this feature. It is submitted that Hubbell does not teach a polymerization accelerator comprising a biocompatible functional group and an N-vinyl group according to these claims.

The Office action on page 5 states that, "Accelerators are disclosed [by] Hubbell *et al.* that contain N-vinyl as in claim 12, and N-vinyl-pyrrolidone disclosed by Hubbell *et al.* contains a carbonyl as in claim 13, an N-vinyl amide as in claim 14, and a heterocyclic ring as in claim 15." While Hubbell disclose accelerators such as N-vinyl pyrrolidinone, 2-vinyl pyridine, 1-vinyl imidazole, 9-vinyl carbazole, acrylic acid and 2-allyl-2-methyl-1,3-cyclopentane dione (claim 30 of Hubbell '870), none of these have a biocompatible functional group and an N-vinyl group according to the claims. Further, Hubbell does not suggest the modification of an accelerator, such as to provide a biocompatible functional group.

With regard to claim 32, Hubbell does not teach a polymerization accelerator comprising a biocompatible functional group, wherein the biocompatible functional group is a sulfonate group.

The Office action states that the polymerization accelerators of Hubbell '914 or Hubbell '870 are inherently capable of binding albumin. Applicants respectfully disagree and assert that this teaching is not found or derivable from Hubbell '914 or Hubbell '870. Hubbell describes albumin in the context of the Examples, where it tests the permeability of PEO gels to albumin (Example 11, Hubbell '870), and in the context of albumin being

a suitable macromer for polymerization. However, upon review of Hubbell '914 or Hubbell '870 there is no description of albumin binding on account of a polymerization accelerator. Further, neither Hubbell '914 nor Hubbell '870 describe a polymerization accelerator having a long-chain fatty acid group such as oleate, stearate, linoleate, or palmitate.

Because Hubbell does not teach or suggest all of the limitations of any one of amended claims 1, 21, or new claim 32, a rejection based on an asserted *prima facie* case of obviousness is not supported. Withdrawal of the rejection is respectfully requested.

#### **Claim 11**

The technical field of Corley '935 or Corley '035 is different than that of Hubbell '914 or Hubbell '870. Corley '935 and Corley '035 are directed to an epoxy resin/amine system which exhibits accelerated cure, using a calcium sulfonate or calcium hydrocarbyl sulfate salt. Corley describes a non-aqueous composition (see claim 1 Corley '935) stated to be useful for coatings and certain civil engineering applications such as for floor topping, grouts and adhesives. Neither Corley '935 nor Corley '035 is directed to biological systems, tissues, or methods for improving biocompatibility.

Corley describes a variety of accelerators for directed epoxy resin/amine system. However, none of these include:

- an N-vinyl group and a biocompatible functional group (as featured in present claim 1 or 21), or
- a sulfonate group which is capable of being introduced into a polymerized product (as featured in new claim 32) to

Further, Corley makes no mention of modifying its accelerators to provide one that can be incorporated into a polymerized product, and that also has a sulfonate group.

Rather, the accelerators of Corley '035 are calcium sulfonates and calcium hydrocarbyl sulfates such as, calcium dodecylbenzene sulfonate, calcium dodecyl sulfate, calcium hexanesulfonate, calcium 3-oxaheptyl sulfate, calcium perfluorooctane sulfonate, and calcium 2-hydroxyoctadecane sulfonate. Corley states that, "The accelerator can be conveniently added to the resin or amine component as a solution in an organic solvent." (Column 2, lines 33-35, Corley '035)

The teachings of both Corley '935 and Corley '035 are clearly divergent from the present invention, or the teaching of Hubbell '914 and Hubbell '870. With an understanding of the teaching of Hubbell, one would not have looked to a reference such as Corley '935 or Corley '035, which makes no reference to biological systems. Furthermore, Corley's use of organic solvents can be dangerous to biological systems and therefore would not be appropriate in the context of the technology provided by Hubbell '914 or Hubbell '870.

Neither Corley '935 nor Corley '035 describe the accelerators of the present invention, and one would not have looked to either reference to supplement the teaching of Hubbell '914 or Hubbell '870 in view of the present claims. In view of the above, an assertion of *prima facie* obviousness is not supported. Withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that all of the claims and the present application are in condition for allowance, which is earnestly solicited. In the event that a phone conference would help resolve any remaining issues in the application, the Examiner is invited to contact the undersigned.

Respectfully Submitted,

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